CERTIFICATE

CERTIFICATE OF COMPLIANCE

NO: 9000434452-EC

Applicant:

ZHENYU TECHNOLOGY(BEIJING)CO.,LTD

UNIT 1, FLOOR 12, BUILDING 3, YARD 1, FUTONG EAST STREET, CHAOYANG DISTRICT, BEIJING, CHINA

Manufacturer:

ZHONGLIANGUOSHANG BIOTECHNOLOGY (BEIJING) CO., LTD

NO.1611, FLOOR 13, BUILDING 5, YARD 10, RONGHUA SOUTH ROAD, BEIJING ECONOMIC AND TECHNOLOGICAL DEVELOPMENT ZONE, BEIJING

Product:

PROTECTIVE MASK

Model:

ZY-FFP1-KN90、ZY-FFP2-KN95 (1)、ZY-FFP2-KN95 (2)、ZY-FFP2-KN95 (3)、ZY-FFP3-KN100、ZY-M (1)、ZY-M(2)、ZY-M(3)、ZY-M(C1)、ZY-M(C2)

Reference to EC Directive:

Regulation (EU) 2016/425
Personal protective equipment (PPE)

Tcf(s) orTest Report(s) No.:

TR-2223-456-9009EN

Relevant standard (s):

EN 149:2001+A1:2009

REMARKS:

Assessment of the product(s) and the production process is not covered by this verification, which has been carried out on a voluntary basis. It is duty and fully responsibility of the manufacturer to carry out all necessary safety assessment of the product(s) according to all related EC Directive and Standard(s) before putting into market/service, affixing CE mark and issue EU Declaration of Conformity. The manufacturer shall affix CE mark on the product(s) according to 2006/42/EC Article 16 and Annex Ⅲ, only if the product(s) fulfill the relevant essential health and safety requirements and the drawn-up EU Declaration of Conformity. Technical File should be drawn for each type/model of related product(s) by the manufacturer and/or his authorized representative in order to assure conformity with the essential health and safety requirements which demonstrate that the machinery complies with the requirements of the related directives/standards and must be complied in one or more official Community languages. Before placing machinery into market/service, the manufacturer or his authorized representative shall ensure that the Technical File in accordance with related directives/standards is available.
The manufacturer or his authorized representative shall keep Technical File and EU Declaration of Conformity available for a period of ten years from the last date of manufacture of the machinery.
The certificate consists of 1(one) page.

The Certificate is valid Until:Mar 21,2025

Date of Issue:Mar 22,2020

CERTIFICATION MANAGER:

LONDON BSI TEST LTD UNITED KINGDOM

CE

BSI TEST LIMITED
Unit G25 Waterfront Studios, 1 Dock Road, London. E16 IAH

EN 149			
Clause	Requirement + Test	Result - Remark	Verdict
1	**Classification**		P
	Particle filtering half masks are classified according to their filtering efficiency and their maximum total inward leakage. There are three classes of devices:	Complied with standard, see appended.	P
	- FFP1		N
	- FFP2		P
	- FFP3		N
2	**Designation**		P
	Particle filtering half masks meeting the requirements of this European Standard. Year of publication, classification		P
3	**Requirements**		P
3.1	In all tests all test samples shall meet the requirements	Complied see bellow	P
3.2	Nomial values and tolerances		P
	Unless otherwise specified,the values stated in this European Standard are expressed as normal values.	Actual using value is clear	P
3.3	Visual inspection		P
	The visual inspection shall also include the marking and the information supplied by the manufacturer.	Clear marking is provided, see sample body	P
3.4	Packaging		P
	Masks shall be offered for sale packaged in such a way that they are protected against mechanical damage and contamination before use.	Distinct design and warning are made on packaging, see sample body	P
3.5	Material		P
	Materials used shall be suitable to withstand handling and wear over the period. Any material from the filter media released shall not constitute a hazard or nuisance for the wearer.	Comfortable wearing, when releasing no hazards is produced	P
3.6	Cleaning and disinfecting		N
	The materials used shall withstand the cleaning and disinfecting	Single-use equipment	N
3.7	Practical performance		P
	The particle filtering half mask shall undergo practical performance tests under realistic conditions.	Complied, see bellow test	P
3.8	Finish of parts	Soft equipment	N

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	Parts likeyl to come into contact with the wearer shall have no sharp edges or burrs		N
3.9	Leakage		P
3.9.1	Total inward leakage		P
	The laboratory tests shall wearer to protect with high probability against the potential hazard to be expected.	Enough safe condition is provide	P
	Exercise results for total inward leakage shall be not greater than 25% for FFP1 11% for FFP2 5% for FFP3	FFP2, See below test table	P
3.9.2	Penetration of filter material		P
	Meet the requirements of Table 1	FFP2 Sodium chloride test: 20% Paraffin oil test: 20%	P
3.10	Compatibility with skin		P
	Materials that may come into contact with the wearer's skin shall not be known to be likely to cause irritation or any other adverse effect to health.	Have no irritation or adverse effect to skin and health	P
3.11	Flammability	Have no such hazard	P
	The material used shall not present a danger for the wearer and shall not be of highly flammable nature.		P
3.12	Carbon dioxide content of the inhalation air		N
	The carbon dioxide content of the inhalation air (dead space) shall not exceed an average of 1,0 % (by volume).	<1.0%	P
3.13	Head harness		
	Head harness shall be designed so that mask can be doned and removed easily.	The design is considered	P
	Head harness shall be adjustable or self-adjusting and sufficiently robust to hold the mask firmly in position .	The design is considered	P
3.14	Field of vision		P
	The field of vision is acceptable if determined so in practical performance tests.	Clear field of vision when wearing	P
3.15	Exhalation valve(s)		P
	A particle filtering half mask may have one or more exhalation valve(s) and shall function correctly in all orientations.	One valve provided	N

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	If an exhalation valve is provided it shall be protected against or be resistant to dirt and mechanical damage and may be shrouded or may include any other device	Clearly function	P
	Exhalation valve(s) shall continue to operate correctly after a continuous exhalation flow of 300 l/min over a period of 30 s.	Complied, see below	P
	Exhalation valve housing is attached to the faceblank, and withstand axially a tensile force of 10 N applied for 10 s.	Enough strong	P
3.16	Breathing resistance		P
	The breathing resistances apply to valved and valveless and shall meet the requirements	Complied, see below test table	P
3.17	Clogging		N
3.17.1	General	Single-use device	N
	For single-use devices clogging test is an optional test.		N
	Devices designed to be resistant to clogging, shown by a slow increase		N
	The specified breathing resistances shall not be exceeded before the required dust load of 833 mg·h/m3 .		N
3.17.2	Breathing resistance		N
3.17.2.1	Valved particle filtering half masks		N
3.17.2.2	Valveless particle filtering half masks		N
	After clogging the inhalation and exhalation resistances shall not exceed - FFP1: 3 mbar - FFP2: 4 mbar - FFP3: 5 mbar		N
	at 95 l/min continuous flow.		N
3.17.3	Penetration of filter materia		N
	All types claimed to meet the clogging requirement shall also meet the penetration requirements given in 7.9.2 after the treatment.		N
3.18	Demountable parts	No any such part	N
	All demountable parts (if fitted) shall be readily connected and secured, where possible by hand.		

4	**Testing**		P
4.1	General		P
	No special measuring devices and methods are specified, commonly used devices and methods	Common methods	P

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	shall be used.		
4.2	Visual inspection		P
	The visual inspection is carried out appropriate by the test house prior to laboratory or practical performance tests.	Considered	P
4.3	Conditioning		P
4.3.1	Simulated wearing treatment		P
	A breathing machine is adjusted to 25 cycles/min and 2,0 l/stroke.	25 cycles/min 2,0 l/stroke.	P
	For testing, a saturator is incorporated in the exhalation line between the breathing machine and the dummy head,	a saturator incorporated by breathing machine and the dummy head	P
	The spilling out of the dummy's mouth and contaminating the particle filtering half mask the head shall be incline	Incline considered	P
4.3.2	Temperature conditioning		P
	Exposet masks to the following thermal cycle:	Complied	P
	a) for 24 h to a dry atmosphere of (70 ± 3) ℃;		P
	b) for 24 h to a temperature of (-30 ± 3) ℃;		P
	Allow to return to room temperature for at least 4 h between exposures and prior to subsequent testing.	5h	P
5	**Marking**		--
5.1	Packaging		P
	The following information shall be clearly and durably marked on the smallest commercially available packaging or legible through it if the packaging is transparent.	Complied, clearly marked	P
5.1.1	The name, trademark or other means of identification of the manufacturer or supplier.	See user manual	P
5.1.2	Type-identifying marking.		P
5.1.3	Classification: FFP1, FFP2, FFP3.	FFP2	P
5.1.4	The number and year of publication of this European Standard.	See above	P
5.1.5	At least the year of end of shelf life.	2 years	P
5.1.6	The sentence 'see information supplied by the manufacturer', at least in the official language(s) of the country of destination, or by using the pictogram as shown in Figure 12b.	English used	

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5.1.7	The manufacturer's recommended conditions of storage (at least the temperature and humidity) or equivalent pictogram, as shown in Figures 12c and 12d.	See user manual	P
5.1.8	The packaging of those particle filtering half masks passing the dolomite clogging test shall be additionally marked with the letter "D".		P
5.2	Particle filtering half mask		P
	Particle filtering half masks		P
	Complying with this European Standard shall be clearly and durably marked with the following:		P
5.2.1	The name, trademark or other means of identification of the manufacturer or supplier.		P
5.2.2	Type-identifying marking.		P
5.2.3	The number and year of publication of this European Standard.	See above	P
5.2.4	The symbols FFP1, FFP2 or FFP3 according to class.	FFP2	P
5.2.5	If appropriate the letter D (dolomite) in accordance with clogging performance. This letter shall follow the class designation (see 9.2.4).		N
5.2.6	Sub-assemblies and components with considerable bearing on safety shall be marked so that they can be identified.		N
6	**Information to be supplied by the manufacturer**		P
6.1	Information supplied by the manufacturer shall be at least in the official language(s) of the country of destination.	English	P
6.2	The information supplied by the manufacturer shall contain all information necessary for trained and qualified persons on - application/limitations; - the meaning of any colour coding; - checks prior to use; - donning, fitting; - use; - maintenance (e.g. cleaning, disinfecting), if applicable; - storage; - the meaning of any symbols/pictograms used of the equipment.	See user manual See user manual	P
6.3	The information shall be clear and comprehensible. If helpful, illustrations, part numbers, marking shall be added.	Clearly considered	P

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6.4	Warning shall be given against problems likely to be encountered, for example: - fit of particle filtering half mask (check prior to use); - it is unlikely that the requirements for leakage will be achieved if facial hair passes under the face seal; - air quality (contaminants, oxygen deficiency); - use of equipment in explosive atmosphere.	See user manual	P
6.5	The information shall provide recommendations as to when the particle filtering half mask shall be discarded.		P

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Attachments: test table

Table 8.5	Leakage test				P
Item \ Models	Sample 1	Sample 2	Sample 3	Sample 4	Sample 5
Test subject walk (km/h)	6	6	6	6	6
Particle size distribution(um)	0.08~1.5	0.08~1.5	0.08~1.5	0.08~1.5	0.08~1.5
NaCl flow rate (L/min)	98~101	98~101	98~101	98~101	98~101
NaCl concentration before mask (mg/m3)	7.9~8.3	7.9~8.3	7.9~8.3	7.9~8.3	7.9~8.3
NaCl concentration after mask (mg/m3)	0.84	0.84	0.85	0.83	0.83
Note: Test ark volume is $2m^3$ Test result total inward Leakage is 9.8%<20%					

Table 8.9-1	Inhalation breathing resistance test at 30 L/min				P
Item \ Models	Sample 1	Sample 2	Sample 3	Sample 4	Sample 5
Inhalation gas velocity (L/min)	30	30	30	30	30
Maximum resistance (mbar)	0.54	0.54	0.53	0.55	0.54
Note: Maximum permitted resistance <0.6 mbar					

Table 8.9-2	Inhalation breathing resistance test at 95 L/min				P
Item \ Models	Sample 1	Sample 2	Sample 3	Sample 4	Sample 5

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Clause	Requirement + Test	Result - Remark	Verdict

Inhalation gas velocity (L/min)	95	95	95	95	95
Maximum resistance (mbar)	1.86	1.86	1.85	1.86	1.85
Note: Maximum permitted resistance <2.1 mbar					

Table 8.9-3	Exhalation breathing resistance test at 160 L/min				P
Models / Item	Sample 1	Sample 2	Sample 3	Sample 4	Sample 5
Exhalation (L/min)	160	160	160	160	160
Maximum resistance (mbar)	2.15	2.16	2.15	2.14	2.14
Note: Maximum permitted resistance < 3.0 mbar					

Appendix
Photo documentation

Photo 1 View: [√] front [ ] rear [ ] right side [ ] left side [ ] top [ ] bottom [ ] internal	

******** End of this report ********